

CERTIFICATE OF ANALYSIS

(Certificate No. KMO001008-01)

Release Date: 22/02/2024

Re-test Date: 21/02/2027

Omeprazole OME VIII

Identification

Chemical Name :

8-methoxy-1,3-dimethyl-12-thioxobenzo[4',5']imidazo[2',1':2,3]imidazo[1,5-a]pyridin-2(12H)-one

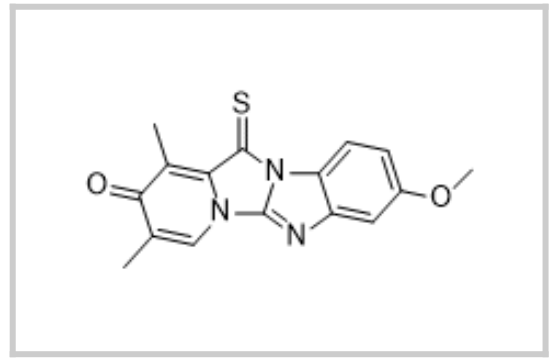
Alt. Name : Omeprazole BP Impurity F , Isomer of Omeprazole EP Impurity G , Omeprazole USP Related Compound F

CAT No. : KMO001008

CAS No. : 125656-82-8

Molecular Formula : C₁₆H₁₃N₃O₂S

Molecular Weight : 311.36



Analytical Information

Batch No. : OME-RCF-073-088

Description : Brown Solid

HPLC Purity : 92.94 %

Weight Loss By TGA : 1.59 %

% Potency : 91.46 %

Solubility : THF

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be shipped at room temperature

% Potency = $[100 - 1.59(\text{Weight Loss By TGA})] \times [92.94(\text{HPLC Purity})]/100 = 91.46 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/02/2024
Reviewed & Approved By	Quality Control	Jatin Patel		22/02/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA